

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	Group Art Unit: 1656
HUTTON et al.)	
)	Examiner: Karen C. Carlson
Application No.: 10/573,280)	
)	Confirmation No.: 4524
Filed: December 21, 2006)	
)	<u>RESPONSE TO RESTRICTION</u>
Attorney Docket No. 2848-56-PUS)	<u>REQUIREMENT</u>
)	
For: USE OF ISLET GLUCOSE-6-)	<i>Submitted Via Electronic Filing</i>
PHOSPHATASE RELATED)	
PROTEIN AS A DIAGNOSTIC)	
TOOL AND THERAPEUTIC)	
TARGET FOR AUTOIMMUNE)	
DIABETES)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

In an Office Action dated May 15, 2008, the Examiner required restriction under
35 U.S.C. §§ 121 and 372 between eight groups:

- Group I -** Claims 1 and 2, drawn to a method of delaying the development of symptoms of diabetes via IGRP;
- Group II -** Claims 3-5, drawn to compositions of IGRP;
- Group III -** Claims 6, 7 and 11, drawn to a method of detecting diabetes via IGRP detection of autoantibodies;
- Group IV -** Claims 6 and 8, drawn to a method of detecting diabetes via IGRP detection of lymphocyte proliferation;

- Group V -** Claims 6, 9 and 10, drawn to a method of detecting diabetes via IGRP detection of lymphocytes that react with MHC class I and MHC class II molecules that are bound to IGRP peptides;
- Group VI -** Claim 12, drawn to a method for screening for IGRP autoantibodies;
- Group VII -** Claims 13-15, drawn to a method to prevent diabetes;
- Group VIII -** Claims 16-17, drawn to a method for treating diabetes.

According to the Office, Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because they lack a special technical feature. Specifically, the Office contends that the method recited in the claims of Group I is not used in the inventions recited in the claims of Groups II-VIII, and, thus, the election of one group is required for prosecution. Office Action, page 2. Applicants respectfully traverse.

Applicants refer the Examiner to M.P.E.P. § 1893.03(d), which sets forth the criteria and guidelines for Examiners to follow in making proper lack of unity of invention requirements. The M.P.E.P. instructs the Examiner as follows:

When making a lack of unity of invention requirement, the examiner **must** (1) list the different groups of claims and (2) explain why each group lacks unity with each other group

M.P.E.P. § 1893.03(d) (emphasis added). In the instant case, the Examiner has only suggested that Group I does not share a special technical feature with Groups II-VIII. The Examiner has not provided any basis for why the inventions in Groups II-VIII should not be examined together. Accordingly, Applicants respectfully request that, at minimum, claims 3-17 of Groups II-VIII be examined in the present application.

Applicants further request that the entire lack of unity of invention requirement be withdrawn because claims 1-17 share a special technical feature and thus relate to a single inventive concept. In particular, claims 1-17 are united by the novel feature that islet glucose-6-phosphatase related protein (IGRP) is a target for autoreactive T lymphocytes in diabetes. The claims thus share the special technical feature of IGRP and compositions comprising the same, which may be used in the prediction (diagnosis), treatment and prevention of diabetes.

Moreover, Applicants note that claims 6-11 of Groups III-V are particularly unified by a single inventive concept in that each claim recites a method to detect diabetes with an IGRP polypeptide. Indeed, these claims are clearly united by linking claim 6. Claims 7-11, each of which depends directly from claim 6, simply recite specific biological responses that may be detected by the IGRP polypeptide and that are indicative of the presence of diabetes. Because these claims meet the unity of invention standard set forth in PCT Rule 13.1 and M.P.E.P. § 1893.03(d), Applicants request that, at minimum, claims 6-11 of Groups III-V be examined together in the present application.

Accordingly, Applicants respectfully request that the lack of unity of invention requirement be withdrawn in its entirety because claims 1-17 are linked by a special technical feature. For the reasons discussed above, Applicants alternatively request that, at minimum, the lack of unity of invention requirement be withdrawn with regard to Groups II-VIII (claims 3-17) and/or Groups III-V (claims 6-11). However, to be fully responsive, Applicants provisionally elect to prosecute Group III, claims 6, 7 and 11 in the instant application.

If the Examiner has any questions regarding this paper, the Examiner is invited to call the undersigned at 303-863-9700. If any fees are due in connection with this paper, please debit Deposit Account No. 19-1970.

Respectfully submitted,

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Dated: June 13, 2008

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